UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,228	11/05/2003	Michael R. Slater	341.030US1	8004

21186 7590 06/30/2006

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
VOGEL, NANCY S	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,228	SLATER ET AL.	
	Examiner	Art Unit	
	Nancy T. Vogel	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to a recombinant vector comprising a recognition site for a first restriction enzyme that generates a 3'TA overhang which is 5' to a recognition site for a second restriction enzyme which generates blunt ends, classified in class 435, subclass 320.1.

II. Claim 13, drawn to a vector comprising a first open reading frame which includes recognition site for a first restriction enzyme that generates a 3'TA overhang and a recognition site for a second restriction enzyme that is not in the open reading frame generates blunt ends, which, once digested with the first and second restriction enzymes and ligated to a fragment comprising a second open reading frame yields a recombinant vector comprising a third open reading frame comprising the first and second open reading frames, which third open reading frame encodes a fusion peptide or protein, classified in class 435, subclass 320.1.

III. Claim 14, drawn to a vector comprising a ribosome binding site which optionally overlaps by one nucleotide with a SgfI recognition site and a recognition site for a first restriction enzyme that generates blunt ends, which vector, once digested with SgfI and the first restriction enzyme and ligated to a DNA fragment comprising an open reading frame encoding a

peptide or polypeptide flanged by SEQ ID NO:2-SEQ ID NO:71 and a blunt end =generated by a second restriction enzyme yields a recombinant vector which encodes the peptide or polypeptide, classified in class 435, subclass 320.1.

IV. Claims 15-19, 23-26, and 27 drawn to a support comprising a plurality of recombinant vectors two or more of which comprise an open reading frame for a different polypeptide, wherein at least one vector comprises a promoter and a first open reading frame which is flanked by two exchange sites wherein the exchange sites are formed by ligation of a vector comprising the promoter which is 5' to a recognition site for a first restriction enzyme that generates a 3'TA overhang which is 5' to a recognition site for a first restriction enzyme which generates blunt ends, which vector is digested with the first and second restriction enzymes and a DNA sequence comprising the first open reading frame flanked by an end generated by SgfI and an end generated by a third restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, and a method of making said support, classified in class 435, subclass 6 (Claims 30-35 are included in this group only as limited to the method of making the support of claim 27).

V. Claims 20, 21 and 23-26, 28, and 30-35 drawn to a support comprising a plurality of recombinant vectors, two or more of which comprise an open

reading frame for a different polypeptide, wherein at least one recombinant vector comprises a promoter and a first open reading frame comprising a second open reading frame and one or more codons which are in=frame with the second open reading frame, wherein the second open reading frame is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a DNA sequence comprising the second open reading frame which includes a PmeI recognition site and is flanked at the 5'end by a recognition site for a first restriction enzyme that generates complementary single-strand DNA overhangs, which DNA sequence is digested with PmeI and the first restriction enzyme , and a vector comprising a blunt end at the 5' end which is s5' to the one or more in-frame codons and the promoter which is 5' to an end generated by a second restriction enzyme which generates single-strand DNA overhangs which are complementary to the single-strand DNA overhangs generated by the first restriction enzyme, and a method of making said support classified in class 435, subclass 6 (Claims 30-35 are included in this group only as limited to the method of making the support of claim 28).

VI. Claims 22-26, and 29-35, drawn to a support comprising a plurality of recombinant vectors, two or more of which comprise an open reading frame for a different polypeptides, wherein at least one recombinant vector comprises a promoter and an open reading frame which is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a

DNA sequence comprising the open reading frame which is flanked by at least two restriction enzyme sites for a first restriction enzyme which is a hapaxoterministic restriction enzyme, which DNA sequence is digested with the first restriction enzyme to generate a first DNA fragment flanked by a first pair of non-self complementary singe-strand DNA overhangs, and a vector comprising the promoter and non-essential DNA sequences that are flanked by two restriction enzyme sites for a second restriction enzyme which is a hapaxoterministic restriction enzyme, which vector is digested with the second restriction enzyme to generate a second DNA fragment which lacks non-essential DNA sequences and is flanked by a second pair of non-self-complementary DNA overhangs is complementary to only one of the single-strand DNA overhangs of the first pair of non-self complementary single-strand DNA overhangs, and a method of making said support, classified in class 435, subclass 6 (Claims 30-35 are included in this group only as limited to the method of making the support of claim 29).

VII. Claim 36, drawn to a method of preparing a plurality of mutagenized recombinant vectors comprising providing DNAs comprising a plurality of mutagenized open reading frames flanked by a SgfI recognition site and a site for a first restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends and digesting the DNAs with SgfI and the first restriction

enzyme and ligating the digested DNAs to a vector comprising a promoter which is 5' to a recognition site for a second restriction enzyme that generates 3'TA overhangs which is 5' to a recognition site for a third restriction enzyme which generates blunt ends, which vector is digested with the second and third restriction enzymes, to yield a plurality of mutagenized recombinant vectors, classified in class 435, subclass 91.52

VIII. Claims 37 and 38, drawn to a method to prepare a plurality of mutagenized recombinant vectors comprising providing DNAs comprising providing DNAs comprising a plurality of mutagenized open reading frames flanked by a recognition site for a first restriction enzyme that generates a 3'TA overhang and site for a second restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, and digesting the DNAs with the first and second restriction enzymes and ligating the digested DNAs to a vector comprising a promoter which is 5' to a SgfI recognition site which is 5' to a recognition site for a third restriction enzyme which generates blunt ends, which vector is digested with SgfI and the third restriction enzyme, to yield a plurality of mutagenized recombinant vectors, classified in class 435, subclass 91.52.

IX. Claims 39, drawn to a method to prepare a plurality of mutagenized recombinant vectors, comprising providing DNAs comprising a plurality of mutagenized open reading frames flanked by two restriction enzyme sites

for a first restriction enzyme which is a hapaxoterministic restriction enzyme and generates a first pair of non-self complementary single-strand DNA overhangs, and digesting the DNAs with the first restriction enzyme and ligating the digested DNAs to a vector comprising a promoter and non-essential DNA sequences flanked by two restriction enzyme sites for a second restriction enzyme which is a hapoxoterministic restriction enzyme, which vector is digested with the second restriction enzyme generating a DNA fragment which lacks non-essential DNA sequences but comprises a second pair of non-self complementary DNA overhangs is complementary to only one of the single-strand DNA overhangs of the first pair of non-self complementary single-strand DNA overhangs to yield a plurality of mutagenized recombinant vectors, classified in class 435, subclass 320.1.

X. Claim 40, drawn to a support comprising a plurality of mutagenized recombinant vectors prepared by the method of 36, classified in class 435, subclass 6.

XI. Claim 40, drawn to support comprising a plurality of mutagenized recombinant vectors prepared by the method of 37, classified in class 435, subclass 6.

XII. Claim 40, drawn to support comprising a plurality of mutagenized recombinant vectors prepared by the method of 38, classified in class 435, subclass 6.

XIII. Claim 40, drawn to support comprising a plurality of mutagenized recombinant vectors prepared by the method of 39, classified in class 435, subclass 6.

XIV. Claims 41, 42 and 67 (as limited to the libraries of 41 and 42), drawn to a library of recombinant cells and vectors, and a library of recombinant vectors, wherein two or more of which recombinant vectors comprise and open reading frame for a different polypeptide, wherein at least one recombinant vector comprises a promoter and a first open reading frame which is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a vector comprising the promoter which is 5' to a recognition site for a first restriction that generates a 3'TA overhang which is 5' to a recognition site for a second restriction enzyme which generates blunt ends, which vector is digested with the first and second restriction enzymes, and a DNA sequence comprising the first open reading frame flanked by an end generated by SgfI and an end generated by a third restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, classified in class 435, subclass 320.1.

XV. Claims 43 and 44, drawn to libraries of recombinant vectors, and recombinant cells comprising said vectors, wherein two or more of said recombinant vectors comprise and open reading frame for a different polypeptide, wherein at least one recombinant vector comprises a

promoter and a first open reading frame comprising a second open reading frame and one or more codons which are in-frame with the second open reading frame, wherein the second open reading frame is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a DNA sequence comprising the second open reading frame which includes a PmeI recognition site and is flanked at the 5' end by a recognition site for a first restriction enzyme that generates complementary single-strand DNA overhangs, which DNA is digested with PmeI and the first restriction enzyme, and a vector comprising a blunt end at the 5' end which is 5' to the one or more in-frame codons and the promoter which is 5' to an end generated by a second restriction enzyme which generates single-strand DNA overhangs which are complementary to the single-strand DNA overhangs generated by the first restriction enzyme, classified in class 435, subclass 320.1.

XVI. Claims 45 and 46, drawn to libraries of recombinant vectors and recombinant cells comprising said vectors, wherein two or more of said vectors comprise an open reading frame for a different polypeptide wherein at least one recombinant vector comprises a promoter and an open reading frame which is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a DNA sequence comprising the open reading frame which is flanked by at least two restriction enzyme sites for a first restriction enzyme which is a hapaxoterministic restriction

enzyme, which DNA sequence is digested with the first restriction enzyme to generate a first DNA fragment flanked by a first pair of non-self complementary single-strand DNA overhangs, and a vector comprising the promoter and non-essential DNA sequences that are flanked by two restriction enzyme sites for a second restriction enzyme which is a hapaxoterministic restriction enzyme, which vector is digested with the second restriction enzyme to generate a second DNA fragment which lacks non-essential DNA sequences and is flanked by a second pair of non-self complementary DNA overhangs is complementary to only one of the single-strand DNA overhangs of the first pair of non-self complementary single-strand DNA overhangs, classified in class 435, subclass 320.1.

XVII. Claims 47, 48, and 67 (limited to the libraries of claims 47 and 48) drawn to libraries of recombinant cells comprising recombinant vectors, and said vectors, wherein a plurality of said vectors comprise mutagenized recombinant vectors comprising mutagenized open reading frames of a selected open reading frame, wherein at least one mutagenized recombinant vector comprises a promoter and a mutagenized open reading frame which is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a vector comprising the promoter which is 5' to a recognition site for a first restriction that generates a 3'TA overhang which is 5' to a recognition site for a second restriction enzyme

which generates blunt ends, which vector is digested with the first and second restriction enzymes, and a DNA sequence comprising the first open reading frame flanked by an end generated by SgfI and an end generated by a third restriction enzyme which has infrequent restriction sites in cDNAs or open reading frames from at least one species and generates blunt ends, classified in class 435 , subclass 320.1.

XVIII. Claims 49 and 50, drawn to libraries of recombinant vectors, and recombinant cells comprising said vectors, a plurality of said vectors comprising mutagenized recombinant vectors comprising mutagenized open reading frames of a selected open reading frame, wherein at least one recombinant vector comprises a promoter and an open reading frame comprising a mutagenized open reading frame and one or more codons which are in-frame with the mutagenized open reading frame, wherein the mutagenized open reading frame is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a DNA sequence comprising the mutagenized open reading frame which includes a PmeI recognition site and is flanked at the 5' end by a recognition site for a first restriction enzyme that generates complementary single-strand DNA overhangs, which DNA is digested with PmeI and the first restriction enzyme, and a vector comprising a blunt end at the 5' end which is 5' to the one or more in-frame codons and the promoter which is 5' to an end generated by a second restriction enzyme which generates single-strand

DNA overhangs which are complementary to the single-strand DNA overhangs generated by the first restriction enzyme,

, classified in class 435, subclass 320.1.

XIX. Claims 51 and 52, drawn to libraries of recombinant vectors and recombinant cells comprising said vectors, wherein a plurality of said vectors comprise mutagenized recombinant vectors comprising open reading frames of a selected open reading frame, wherein at least one recombinant vector comprises a promoter operably linked to the mutagenized open reading frame which is flanked by two exchange sites, wherein the exchange sites are formed by ligation of a DNA sequence comprising the mutagenized open reading frame which is flanked by at least two restriction enzyme sites for a first restriction enzyme which is a hapaxoterministic restriction enzyme, which DNA sequence is digested with the first restriction enzyme to generate a first DNA fragment flanked by a first pair of non-self complementary single-strand DNA overhangs, and a vector comprising the promoter and non-essential DNA sequences that are flanked by two restriction enzyme sites for a second restriction enzyme which is a hapaxoterministic restriction enzyme, which vector is digested with the second restriction enzyme to generate a second DNA fragment which lacks non-essential DNA sequences and is flanked by a second pair of non-self complementary DNA overhangs is complementary to only one of the single-strand DNA overhangs of the first pair of non-self

complementary single-strand DNA overhangs, classified in class 435, subclass 320.1.

XX Claims 53-65, drawn to a method to introduce at least two recognition sites for at least two different restriction enzymes to the ends of an open reading frame comprising providing one or more nucleic acid sequences each comprising an open reading frame and amplifying each nucleic sequence, classified in class 435, subclass 91.52.

XXI. Claim 66, drawn to recombinant cells prepared by transforming cells with a recombinant vector made by the method of claim 65, classified in class 435, subclass 252.3.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups VII, VIII, IX and XX are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods comprise different and distinct steps: providing DNAs comprising a plurality of mutagenized open reading frames flanked by a SgfI recognition site (Group VII); providing DNAs comprising a plurality of mutagenized open reading frames flanked by a recognition site for a first restriction enzyme that generates a 3'TA overhang (Group VIII); providing DNAs comprising a plurality of mutagenized open reading frames flanked by two restriction enzyme sites for a first restriction enzyme

which is a hapaxoterministic restriction and generates a first pair of non-self complementary single-strand DNA overhangs (Group IX); amplifying each nucleic acid sequence with at least a pair of oligonucleotides (Group XX)

Inventions of Groups VIII, IX and XX and XVII, XVIII, XIX, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products can be made by a materially different process, such as by in vitro chemical synthesis.

Inventions of Group XX and XXI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a materially different process, such as by in vitro chemical synthesis.

Except for the specific relationships described above, the invention of Groups I-VI, X-XIX, XXI and Groups VII-IX and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04,

MPEP 808.01). In the instant case the different products of Groups I-VI, X-XIX, XXI are not used in or made by the methods of Groups VII-IX and XX.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further more, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NV
6/15/06

NANCY VOGEL
PRIMARY EXAMINER